

KASPER Controlled Substance Reporting Guide

Cabinet for Health and Family Services Office of Inspector General

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Document Purpose

One of the largest threats to patient safety in the Commonwealth of Kentucky is the misuse, abuse and diversion of controlled pharmaceutical substances. The Kentucky All Schedule Prescription Electronic Reporting System (KASPER) is Kentucky's Prescription Drug Monitoring Program. KASPER is housed in the Office of Inspector General in the Cabinet for Health and Family Services (CHFS). KASPER is intended as a tool to help health care providers identify patients at risk of a substance use disorder, and to assist authorized law enforcement and regulatory agencies with drug investigations. Kentucky statutes and regulations require the reporting to KASPER of Schedule II through V controlled substance medications administered or dispensed in Kentucky.

This guide provides information on the following:

- Kentucky statutes and regulations requiring reporting to KASPER
- Establishing a KASPER uploader account
- Data reporting guidelines and transmission methods for KASPER
- Preparing and transmitting data
- Using the web-based prescription data entry form
- Upload reports
- Error thresholds and tolerances
- Error correction requirements
- KASPER contact information

This guide should be used by all practitioners and dispensers who are required to report administered or dispensed controlled substance data to KASPER.

Kentucky Revised Statute 218A.202 and Kentucky Administrative Regulation 902 KAR 55:110 establish the legal requirements for reporting Schedule II through V controlled substances to CHFS, and are included in Appendix A, KASPER Statute and Regulation.

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1 Registration and Reporting Requirements

1.1 Registration Requirements

- All dispensers licensed by the Kentucky Board of Pharmacy that possess a DEA license **must** register as KASPER data reporters.
- Practitioners who administer or dispense controlled substances **must** register as KASPER data reporters.
- Practitioners who **never** administer or dispense controlled substances are **not** required to register as KASPER data reporters.
- Veterinarians are **not** required to register or report controlled substance dispensing to KASPER.

1.2 Uploader Account Security

• Each individual who will upload data, either through file upload or the prescription data entry form, must obtain his or her own uploader account, and agree not to share login credentials with others.

1.3 Reporting Requirements

- Reporting is required for any practitioner or pharmacy that administers or dispenses a
 Schedule II V controlled substance to a human patient.
- Dispensers and practitioners are required to report dispensed or administered controlled substance data no later than the close of business on the business day immediately following the dispensing or administration.
- Kentucky does not require zero reports. Reporting is only required when a controlled substance has been administered or dispensed as defined in KRS 218A.202 and 902 KAR 55:110.

1.4 Data Reporting Exceptions

The following are the only exceptions to the data reporting requirement:

- A drug administered directly to a patient in a hospital, a resident of a healthcare facility licensed under KRS Chapter 216B, a resident of a child-caring facility as defined by KRS 199.011, or an individual in a jail, correctional facility, or juvenile detention facility.
- A Schedule III through Schedule V controlled substance dispensed by a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours and is not dispensed by the emergency department of a hospital.
- A drug administered or dispensed to a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections where the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health.

1.5 Reporting Non-Compliance

 Under KRS 218A.202, intentional failure by a dispenser to transmit data to the KASPER program as required shall be a Class B misdemeanor for the first offense, and a Class A misdemeanor for each subsequent offense.

1.6 Data Reporting Waivers

 Dispensers with a DEA license who certify that they do not dispense any controlled substances in Kentucky must register as a KASPER data reporter. However, once registered CHFS can provide a reporting waiver email. Dispensers can request a reporting waiver by contacting KASPER staff at eKASPER.Admin@ky.gov.

2 Account Registration and Management

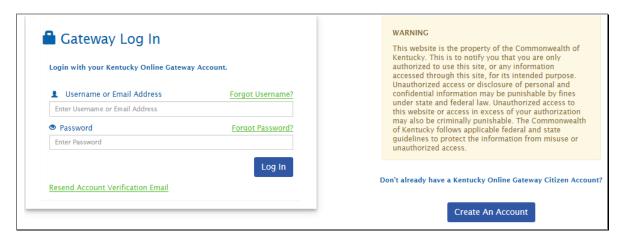
2.1 Creating an Uploader Account

2.1.1 Creating a Kentucky Online Gateway Account

1. In your browser, go to https://ekasperupload.chfs.ky.gov/GetStarted.aspx to access the KASPER Data Reporting website for account registration.

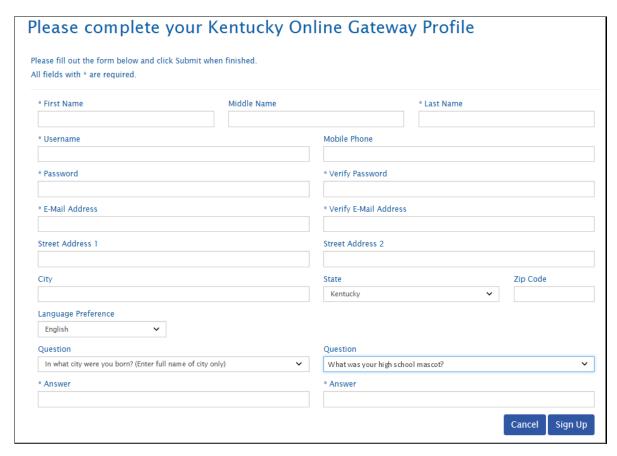


2. Click on **Get Started**, which will take you to the Kentucky Online Gateway page.



3. When you get here:

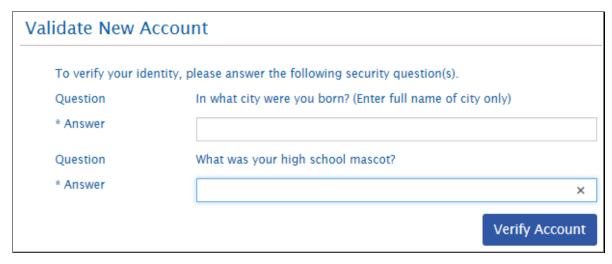
- a. If you already have a Kentucky Online Gateway account, enter your Username and Password on the left and click **Log In**, then skip to Step 9.
- b. If you do not already have a Kentucky Online Gateway account, click the **Create An Account** button to begin creating your Kentucky Online Gateway account.



4. Complete all required fields (marked with a *) and any optional fields you wish to complete, then click **Submit**.



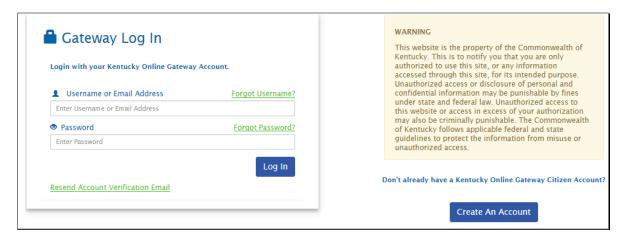
5. Log in to the email account which you provided, and look for an email from Kentucky Online Gateway. The subject should include the words "Account verification". In the email there should be a link to click on to verify your Kentucky Online Gateway account.



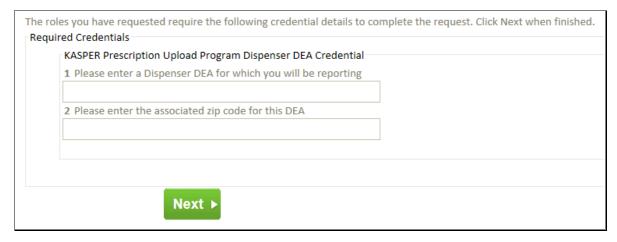
6. A new tab or window should open in your browser, asking you to provide the answers to the security questions you specified earlier when setting up the account. Enter the answers and click **Verify Account**.



7. Click on Continue to Logon to proceed.

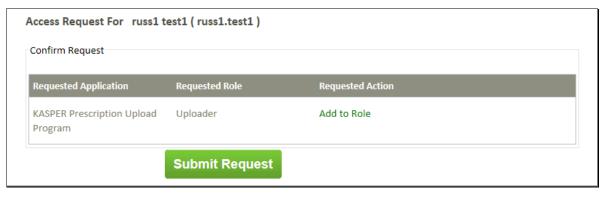


8. Back on the **Gateway Log In** screen, on the left, enter the username and password that were established earlier when setting up the account, and click **Log In**.



 On the New Account Registration screen, enter the DEA number of any dispenser or dispensing practitioner (if you report for many, just choose one) for whom you will be reporting data, as well as the ZIP Code associated with that dispenser, and then click Next.

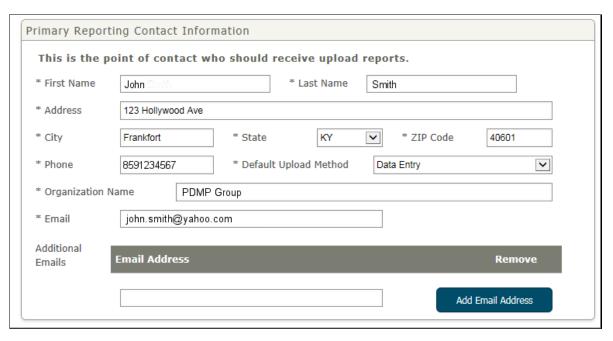
Note: The ZIP code entered must match the ZIP code listed for that DEA number in the Drug Enforcement Administration database, or the system will provide an error message indicating an Invalid DEA/ZIP Code.



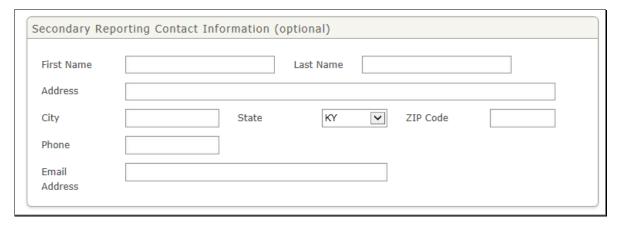
10. Click on the **Submit Request** button. You will then be taken to the KASPER Prescription Upload Program to complete the registration process.

2.1.2 Prescription Upload Program Registration

Once your Kentucky Online Gateway account registration is complete, you must also register with the KASPER Prescription Upload Program. This is a one-time-only registration.



- 1. Take the following steps under **Primary Reporting Contact Information**:
 - a. Complete all required fields (marked with a *) in the **Primary Contact Information** area of the form. This contact is the person who will receive upload report notification emails, and will be the primary contact for the KASPER Team. Some fields which you already entered for the Kentucky Online Gateway account may already be filled in here.
 - b. For the **Default Upload Method**, select either *Data Entry*, *File Upload* or *Secure FTP* to set your primary reporting method. Each time you log in, the system will automatically take you to the appropriate web page for the default reporting method you select to save you time. You can always access other upload methods via the navigation menu.
 - c. The optional **Additional Emails** area allows you to provide up to 5 additional email addresses of people who will also receive upload report notifications.

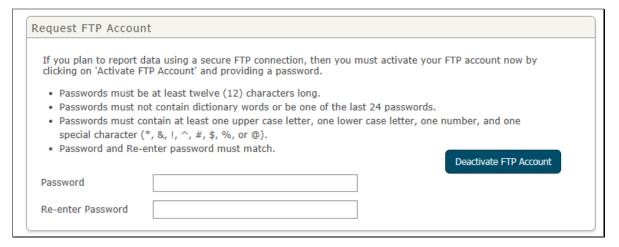


2. Optionally, you may provide a **Secondary Contact**. This individual will only be contacted by the KASPER Team in the event that the primary contact is unavailable, and will

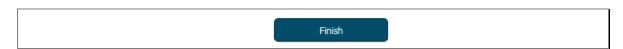
receive no notification emails (unless their email address is also included in the **Additional Emails** section above).



3. If you plan to submit data files via secure FTP, then you should activate your FTP account by clicking on **Activate FTP Account**, which will change the contents of that section of the form. If you do not plan to submit via FTP, you can safely ignore this section and skip to Step 5.



- 4. To complete FTP account activation, create a password and enter it in both fields. Your password *does not expire* once set, and must meet these requirements:
 - a. Is at least 12 characters long
 - b. Contains at least one upper case letter, one lower case letter, one number and one special character (*, &, !, ^, #, \$ or %)
 - c. Does not contain any dictionary words
 - d. Is different from your previous 24 passwords



5. When all required actions are completed, click **Finish**.



6. You are now registered and ready to upload prescription data to KASPER. If you activated your FTP Account, your FTP account name will also be provided here, and can also always be found later under your **Account Profile**. Click **Continue** to go to your default upload method.

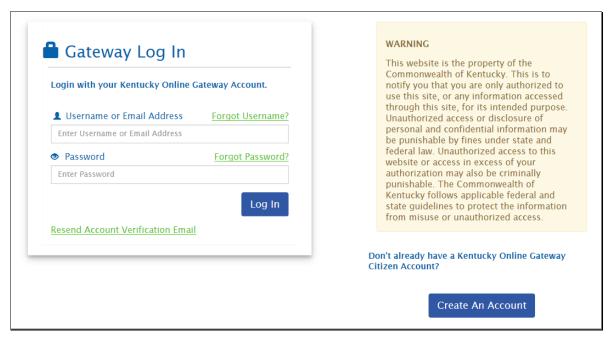
2.2 Login Procedure

2.2.1 Logging In To An Existing Account

Once you have completed registration, you can log in to upload data by following these steps.

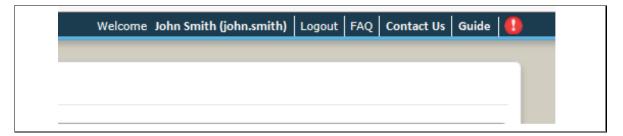
1. In your browser, go to https://ekasperupload.chfs.ky.gov/Default.aspx to access the KASPER Data Reporting website. You should immediately be redirected to the Kentucky Online Gateway login page.

Important: Do not go to the Get Started page you used for registration.



- 2. On the left side, enter the Gateway account name and the password you created during registration, and click **Log In**.
- 3. Once authenticated, you will be taken back to the KASPER Data Reporting webpage and should arrive at either the **File Upload** screen or the **Prescription Data Entry Form** screen, depending on the preference you set during registration. If you chose *Secure FTP* as your default upload method, you will be taken to your account profile page, since FTP is a separate protocol not done through the web page. Be sure to note your FTP account name which will be displayed at the bottom of that page.

2.2.2 Status Toolbar



- Once logged in, you will see a toolbar in the upper right of the web page. You can use
 the toolbar to verify which account you are logged into, as well as log out of the system,
 view the FAQ, contact the KASPER Team, or get the latest version of the reporting guide
 (this document).
- If you see an alert icon at the right end of the toolbar, you can click it to bring up any
 messages from the KASPER Team which may be advising you of upcoming scheduled
 downtime or other system messages.

2.2.3 Navigation Menu

Once logged in, you will see the navigation menu on the left side of the screen. Use this to easily and quickly access any part of the KASPER Data Reporting website needed.

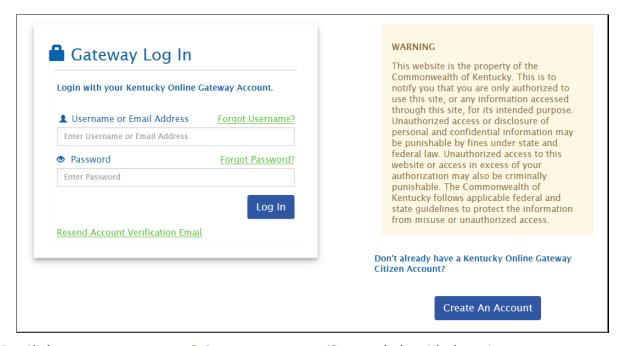


- 1. **Account Profile** will allow you to edit your account settings, such as contact information.
- 2. **File Upload** is where you can upload a data file for processing.
- 3. **Rx Data Entry Form** is a way to report prescription data by entering the data through a web page.
- 4. **Upload Reports** will allow you to search for your uploaded data files regardless of how you submitted them, and access the upload (error) reports associated with each file.

2.2.4 Forgotten Username or Password

If you forget your Kentucky Online Gateway username or password, take these steps:

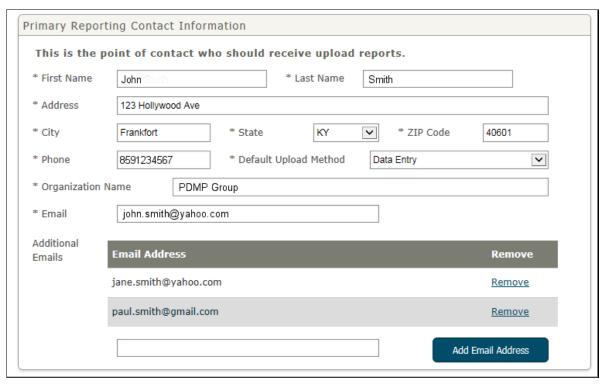
1. In your browser, go to https://ekasperupload.chfs.ky.gov/Default.aspx to access the KASPER Data Reporting website. You should immediately be redirected to the Kentucky Online Gateway login page.



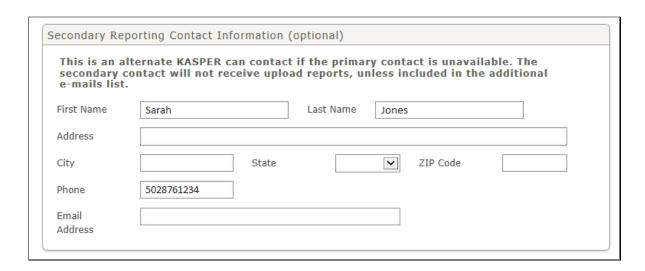
2. Click on Forgot Username? Or Forgot Password? to get help with these issues.

2.3 Editing Your Account Profile

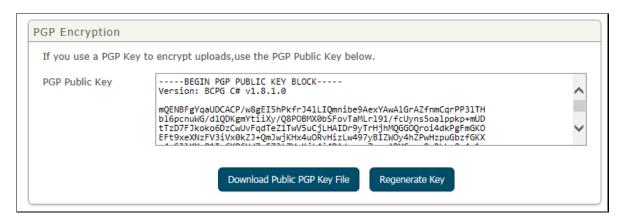
1. At any time while logged in to the Data Reporting Website, click on **Account Profile** on the left navigation menu.



- 2. Under **Primary Reporting Contact Information**, review the information and make any changes necessary.
 - a. You can manage the **Additional Emails** section by entering a new address in the text box and clicking **Add Email Address** to add that email address to the list.
 - b. You can remove any address in the list by clicking the **Remove** link for that address.



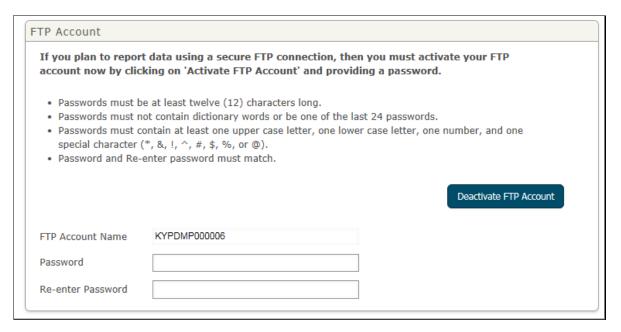
3. Under **Secondary Reporting Contact Information**, review and update any of this optional information.



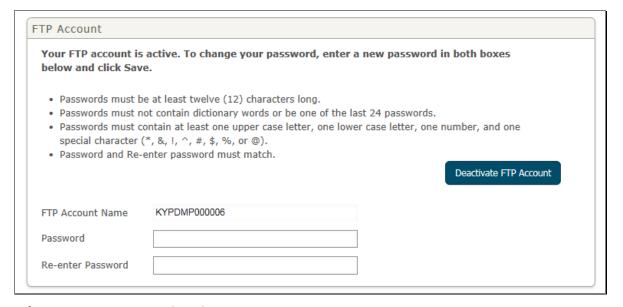
- 4. If you intend to encrypt uploaded data files, you will need the PGP Public Key found in this section.
 - Click **Download Public PGP Key File** to download the key file, to import into your PGP Keyring.
 - b. Click on Regenerate Key only if your key security has been compromised and you need a new one. Note that once the key is changed, <u>all</u> future uploads must be encrypted with the new key, or else KASPER will be unable to decrypt your files. Furthermore, any file already uploaded with the old key but not yet successfully processed by KASPER will have to be uploaded again after being encrypted with the new key.
 - c. For more information, see **Using OpenPGP Encryption** elsewhere in this document. If you do not encrypt your files or aren't sure what this is, you can safely ignore this section.



5. If you have not activated your FTP account and need to do so now, click on **Activate FTP Account**, which will change the contents of that section of the form.



6. To complete FTP account activation, create a password and enter it in both fields. Your password must meet the requirements displayed on the screen.



- 7. If your FTP account is already active:
 - a. You will see your FTP account name here. You must use this account name and your current password to connect to the FTP server to upload files.
 - b. If you need to change your password, enter a new one in both fields, adhering to the password complexity rules displayed on the screen, then click **Save** below.
 - c. Click on **Deactivate FTP Account** if you no longer will use FTP to upload files. Note that if you do this, you will no longer be able to log in to the FTP server.

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3 Data Reporting

Data can be reported by several different methods.

- A data file can be created and uploaded using either SFTP in your FTP client program, or through the KASPER Data Reporting website.
- Low volume reporting and record revisions can be entered using the **Prescription Data Entry Form** on the KASPER Data Reporting website.

3.1 Data File Upload

3.1.1 Data File Format

Data files to be uploaded must observe these requirements, which have not changed from the previous implementation:

- The filename is expected to be the date of upload in YYYYMMDD format, with no spaces, and a .dat extension if unencrypted; if encrypted with your **PGP Public Key**, the file should have a .pgp or .gpg extension, depending on your encryption software.
- Multiple file uploads per day require a suffix such as "_1", "_2", etc. to distinguish the different files uploaded on that day.
- The data in the file must adhere strictly to the ASAP 4.2 data standard. Refer to Section 3.3 Required Data Elements, as well as the <u>ASAP 4.2 Standard</u> documentation, for full details on data structure and content.

3.1.1.1 Using OpenPGP Encryption

You may encrypt the file using OpenPGP if you choose, which will help secure the file once it resides on the FTP Server.

- 1. To find your **PGP Public Key**, log in to the KASPER Data Reporting website and find it under your **Account Profile**.
- 2. Download the key file, then import the PGP public key into your PGP key ring.
- 3. Encrypt the file using the PGP software of your choice. The file should have a .pgp or .gpg file extension.

3.1.1.2 Using ZIP File Compression

- A single .dat file may be archived in a .zip archive and given the same name as the .dat file, to reduce file size and transfer time.
- Do not put more than one data file inside a given .zip file. If you have multiple .dat files to upload, archive them individually into separate .zip files.
- PGP encryption also compresses your .dat file, so there is no reason to archive your .pgp or .gpg file into a .zip file; just upload the encrypted .pgp or .gpg file.

3.1.2 File Upload Via FTPS (using SSL)

You can submit a data file via our secure FTP server. Note that unsecure FTP connections are **not** supported.

1. Prepare the file as described above.

- 2. Make sure you have activated your FTP account. If you did not do so during account registration, you can do so at any time on your **Account Profile** page.
- 3. In your FTP client, go to ftp.ky.gov.
 - a. If you need to use a full connection URL, use ftps://ftp.ky.gov since our server uses SSL.
 - b. If your FTP client requires a port, use the default FTPS port 21.

Note: Do <u>not</u> go to <u>https://ftp.ky.gov/</u> in a web browser, as **Prescription Upload Program** user accounts are not authorized to use that interface, and you will be unable to log in there. You must use an FTP client and the secure FTP protocol.

- 4. Enter your FTP account login information to authenticate to the secure FTP server. Your FTP account name can be found on your **Account Profile** page.
- 5. Upload the data file.

Important: Our FTP server may also use ports 3000-3003 for data transfer, so open those in your firewall if necessary.

6. Log off when file upload is complete.

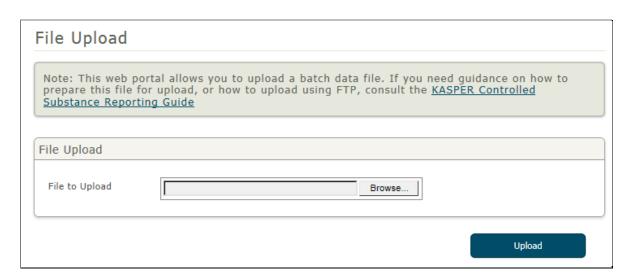
3.1.3 File Upload Via SFTP (using SSH)

Authenticating using SSH is not enabled on FTP accounts by default. If you require an SSH connection and have an SSH Public Key to provide to KASPER, then please contact the eKASPER Help Desk and tell them you need to have SSH enabled and they will put you in touch with the right person.

3.1.4 File Upload Via Secure Website

Files may be uploaded for processing through our secure web portal.

- 1. Log in to the KASPER Data Reporting website as directed under Logging In To An Existing Account.
- 2. Select *File Upload* from the navigation menu under **Data Reporting**. You should already start there if you configured your **Default Upload Method** to *File Upload*.



- 3. Click the *Browse* button and locate the data file (either a .dat, .pgp, .gpg or .zip file) to be uploaded on your local file system.
- 4. Click **Upload** to upload the file to the KASPER server.



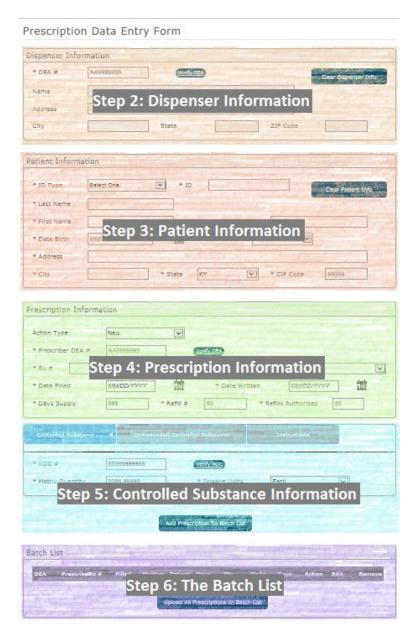
5. You will see the above message when the upload is complete, and will receive an email message from KASPER when the upload report is available.

3.2 Prescription Data Entry Form

The **Prescription Data Entry Form** allows you to enter individual prescription records one at a time to build a small batch of records, and then submit it to KASPER. It is not intended for moderate to high volume reporting, due to its manual nature.

3.2.1 Form Layout

The form itself is large and has several sections. The image below shows all sections, and indicates which ones are covered by each step below to assist you in learning how to use it.



3.2.2 Step One: Login

Log in to the KASPER Data Reporting website as directed under Logging In To An Existing Account.

• Select **Rx Data Entry Form** under **Data Reporting** from the navigation menu. You should already start there if you configured your **Default Upload Method** to *Data Entry*.

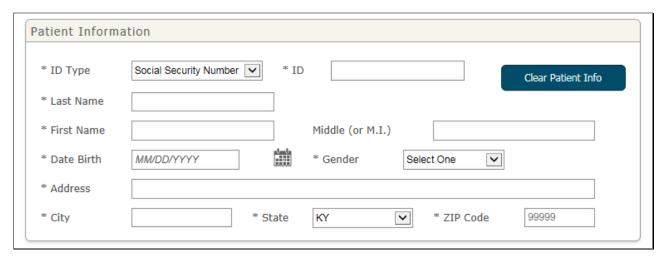
3.2.3 Step Two: Enter Dispenser Information



- In the **Dispenser Information** section, enter the DEA number of the dispensing entity or practitioner and then click elsewhere or hit the Tab key. The system will look up the rest of the information and fill it in for you. Multiple address lines in the DEA record will be combined into the address value shown here.
- This is a required field; the DEA **must** be known to the system in order to proceed.
- You can click Clear Dispenser Info at any time to clear the section.

Note: The name and address information comes directly from the DEA. If any of this information is incorrect, it must be addressed and corrected with the DEA, and **not** with the KASPER team.

3.2.4 Step Three: Enter Patient Information



• In the **Patient Information** section, complete all fields for the patient who received the prescription.

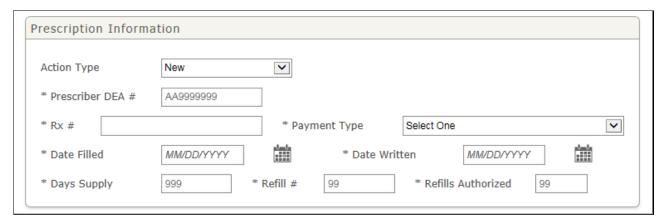
Note: The **Middle (or M.I.)** field may be left blank if the middle name or initial is unknown, or the patient has no middle name.

- For the ID field, enter the patient's Social Security Number (SSN).
 - o If the patient does not have a **SSN**, change the **ID Type** dropdown to *Driver's License Number* and enter a valid driver's license number for the **ID** instead.
 - If the patient does not have a SSN or driver's license, enter 000000000 (nine zeroes) for the SSN.

Note: **Kentucky regulation 902 KAR 55:110 Section 5** requires that a patient disclose their SSN to the dispenser for purposes of reporting to KASPER. Only if the patient does not have a SSN may a driver's license or zeros be reported.

• You can click **Clear Patient Info** at any time to clear the section.

3.2.5 Step Four: Enter Prescription Information



- Use the **Action Type** to indicate whether the prescription is a new record, a revision to an existing record, or an existing record which you wish to void.
- Date Filled and Date Written must be later than the patient's date of birth.
- Enter the Prescriber DEA number and then click elsewhere or hit the Tab key. The
 system will attempt to look up the name of the prescriber and display it besides the
 DEA. This helps you to be sure you've entered the DEA number correctly.

Note: The prescriber name comes directly from the DEA. If it is incorrect, it must be addressed and corrected with the DEA, and **not** with the KASPER team.

IMPORTANT: Do not submit a DEA number beginning with 'X', also known as a data waiver DEA number. These numbers will be rejected by the system. You must provide a standard DEA number for the prescriber.

Complete the rest of the required information about the prescription.

3.2.6 Step Five: Enter Controlled Substance Information

For each prescription, choose either the *Controlled Substance* or the *Compounded Controlled Substance* tab, depending on whether or not the prescription is compounded. The *Instructions* tab has a summary of the instructions found here for easy reference.

3.2.6.1 NDC Number Formatting

Records **must** be submitted using the correct 11-digit National Drug Code (NDC) number. The actual 11 digit NDC number includes three segments in a 5-4-2 format: 99999-999-99. Some drugs may show a 10-digit Health Related Item (HRI) code or Universal Product Code. Converting a 10-digit code to the correct 11-digit NDC format may require including a leading zero in one of the segments. The following table provides examples for converting a

10 digit NDC code to the 11-digit code based on the placement of the leading zero in the proper segment.

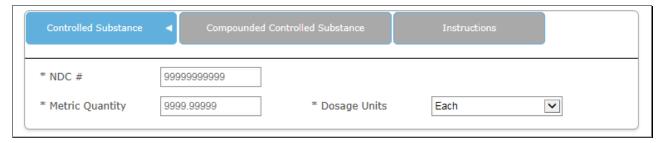
Note: The hyphens are shown below only to illustrate the segment format examples. **Do not use** hyphens when entering the NDC Number in the Data Entry Form.

	10 Digit Format on Product	10 Digit Format Example	Correct 11 Digit NDC Format	Correct 11 Digit Format Showing Insertion of Leading Zero			
NDC F	NDC Format on Product						
	4-4-2	9999-9999-99	5-4-2	<mark>0</mark> 9999-999-99			
	5-3-2	99999-999-99	5-4-2	99999- <mark>0</mark> 999-99			
	5-4-1	99999-9999-9	5-4-2	99999-9999- <mark>0</mark> 9			
HRI Fo	rmat on Product						
	4-6	9999-999999	5-4-2	<mark>0</mark> 9999-9999-99			
	5-5	99999-99999	5-4-2	99999- <mark>0</mark> 999-99			
UPC Fo	UPC Format on Product						
	5-5	99999-99999	5-4-2	99999- <mark>0</mark> 999-99			

An even more thorough **NDC Information Sheet** is available <u>here</u>.

3.2.6.2 Non-compounded Prescriptions

For typical prescriptions which are not compounded, use this tab to report the controlled substance ingredient in the prescription.



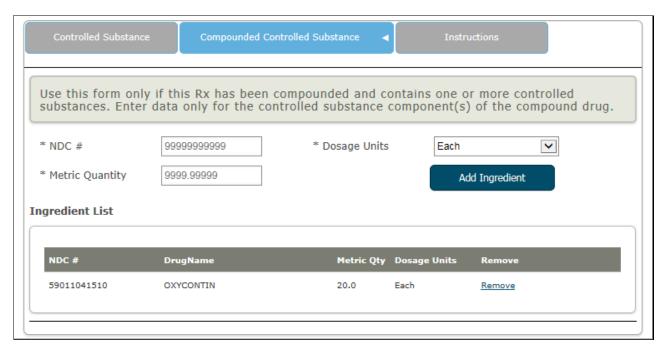
• Enter the NDC number and click elsewhere, or hit the Tab key. The system will attempt to look up the name of the drug and add it to the right of the NDC number. This helps you to be sure you've entered the NDC number correctly.

Note: If you feel there is a problem with the displayed drug name, please contact KASPER Program Support.

• Provide the Metric Quantity, then select the applicable Drug Dosage Units.

3.2.6.3 Compounded Prescriptions

Use this tab for compounded prescriptions *only*. Also, you only need to report here those ingredients in the compound *which are controlled substances*.



- Add all *reportable* ingredients to the list by following the steps below. Ingredients which are not controlled (i.e. not required to be reported) should not be added.
- Enter the NDC Number and Metric Quantity, then select the applicable Dosage Units.
- Click **Add Ingredient** to add that ingredient to the table. The *Drug Name* is looked up automatically based on the NDC you provide.

Note: If you feel there is a problem with the displayed drug name, please contact KASPER Program Support.

You can click <u>Remove</u> to remove that ingredient from the table.

3.2.6.4 Add Prescription To Batch List

- When each prescription's information is complete, click **Add Prescription To Batch List** to add it to the list.
- Use the **Clear Dispenser Info** and **Clear Patient Info** buttons in the first two sections as needed when you switch to different dispensers and patients.
- Repeat the process to construct a full list of all prescriptions to be reported.

3.2.6.5 Validation Error Messages

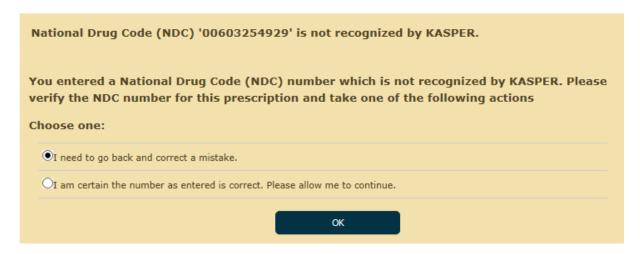
Whenever you click **Add Prescription To Batch List**, the system will validate all of the values you have entered. If you make any errors filling out the form, those errors will usually be listed in a red box at the top of the page (some appear embedded in the form in yellow boxes; see the next section). An example:



- Prescriber DEA Number is a required alphanumeric field. Enter in AA9999999 format (2 letters followed by 7 numbers). The first letter must be A, B, F, or M; DEA numbers with data waivers (those beginning with X) are not allowed.
- Date Filled must not be earlier than Date Written.
- A selection must be made for 'Payment Type'

3.2.6.6 Other Error Messages

Depending on the data you enter and records which already exist in the system, there may be conflicts which alert you to errors in the data you entered, or require you to clarify your intentions. Below are some of the error messages which you may encounter when trying to **Add Prescription To Batch List**, and how to act on them.



- If you enter an NDC number for a controlled substance which KASPER does not recognize, you will see this message.
- Double check the number you entered and make certain it is a valid NDC number. If you
 made a mistake, select the first option and click **OK** to return to the form and edit the
 NDC value. If you are certain it is valid, select the second option and click **OK**, and the
 NDC value will be accepted as entered.

Prescriber DEA # Not Found. Please enter 2 letters followed by 7 numbers (AA9999999). The first letter must be A, B, F, or M; DEA numbers with data waivers (those beginning with X) are not allowed.

You entered a Prescriber DEA number which is not recognized by KASPER.

Please verify the Prescriber DEA number for this prescription and take one of the following actions

Choose one:

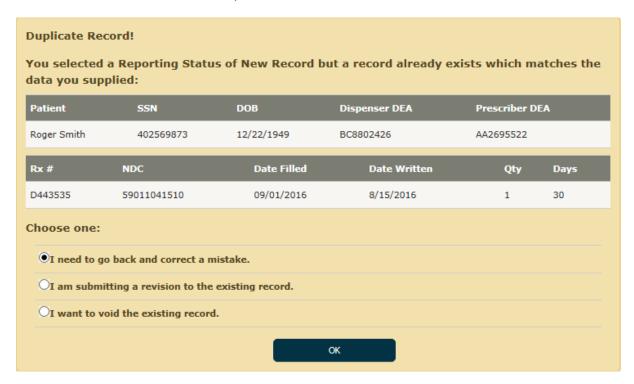
OI need to go back and correct a mistake.

OI am certain the number as entered is correct. Please allow me to continue.

If you enter Prescriber DEA number which KASPER does not recognize, you will see this
message.

Note: This applies only to prescriber DEA numbers; dispenser DEA numbers must be known to KASPER.

 Double check the number you entered and make certain it is the correct DEA number. If you made a mistake, select the first option and click **OK** to return to the form and edit the DEA value. If you are certain it is valid, select the second option and click **OK**, and the DEA value will be accepted as entered.

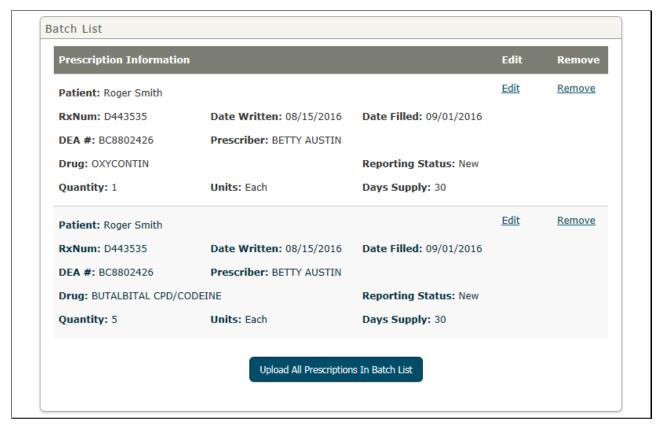


- If you select New Record but enter information all of which matches an existing record, you will see this message.
- If the conflict was caused due to entering erroneous information, select the first option and click **OK** to return to the form and make corrections.
- If you intended to *revise* the existing record but simply forgot to select *Revise Record* for the **Action Type**, then select the second option and click **OK**, and that change will be made automatically and the record added to the **Batch List** as a *Revise Record* action.
- If you intended to *void* the existing record but simply forgot to select *Void Record* for the **Action Type**, then select the third option and click **OK**, and that change will be made automatically and the record added to the **Batch List** as a *Void Record* action.



- If you select *Void Record* but the information fail to match an existing record, you will see this message.
- If the issue was caused due to entering erroneous information, select the first option and click **OK** to return to the form and make corrections.
- If you intended to submit a new record but mistakenly selected *Void Record* for the **Action Type**, then select the second option and click **OK**, and that change will be made automatically and the record added to the **Batch List** as a *New Record* action.

3.2.7 Step Six: Review the Batch List and Upload the Data



- Each time you click Add Prescription To Batch List, if there are no errors on the form, a
 new prescription record is added to the Batch List table at the bottom of the form. The
 details of that prescription depend on whether the Controlled Substance or
 Compounded Controlled Substance tab is selected when you click Add Prescription To
 Batch List.
- If you click Edit on any prescription in the table:
 - The form values (in all sections, including Dispenser Information and Patient Information) are populated with that row's data, and the Add Prescription To Batch List button is replaced with Save and Cancel buttons.
 - Make any needed changes to the prescription, then click Save to save the changes.
 - o Click on **Cancel** if you change your mind and do not need to make any changes.
- You can click <u>Remove</u> on any prescription in the Batch List to remove it from the list.

Note: The removal process cannot be undone!

When all the prescription records you need to report are in the Batch List, click on
 Upload All Prescriptions In Batch List to upload the data to KASPER for processing. The
 system will inform you of the success or failure of the upload.

IMPORTANT! The records in the batch list are not sent to KASPER until you click on Upload All Prescriptions In Batch List!

3.3 Required Data Elements

All submitted data must adhere to the ASAP 4.2 Standard, and also include any additional Kentucky-required values listed in the table below, which lists the complete set of <u>required</u> values.

Complete information on the ASAP 4.2 Standard for prescription monitoring programs is available directly from the American Society for Automation in Pharmacy, at http://www.asapnet.org/pmp-implementation-guides.html, in the Implementation Guide ASAP Standard For Prescription Monitoring Programs.

3.3.1 Data Element Table

The **Format** codes for the table are the following:

AN = alphanumeric

D = Metric decimal

DT = Date format: CCYYMMDD

N = Numeric

TM = Time format: HHMMSS or HHMM

ASAP 4.2 Element ID	Name	Usage	Specifications	Format	Max Length			
TH Transac	TH Transaction Header							
TH01	Version/Release Number	Required	Always populate with "4.2"	AN	4			
TH02	Transaction Control Number	Required	Unique transaction identifier	AN	40			
TH05	Creation Date	Required	Formatting = CCYYMMDD	DT	8			
TH06	Creation Time	Required	Formatting = HHMMSS, HHMM	TM	6			
TH07	File Type	Required	P = ProductionT = Test	AN	1			
TH09	Segment Terminator Character	Required	Any allowed terminator character (see the ASAP 4.2 specification), although most commonly, the tilde ~ is used. Indicates to the system that this segment has ended. This character must also be used to terminate every subsequent segment.	AN	1			

ASAP 4.2 Element ID	Name	Usage	Specifications	Format	Max Length
IS Informa	tion Source				
IS01	Unique Info Source ID	Required	Always populate with "KY"	AN	10
ISO2	Info Receiver Entity Name	Required	Always populate with "PMP Program"	AN	60
PHA Pharr	nacy Header				
PHA01	Pharmacy NPI	Situational	Used if supplied, but not required.	AN	10
PHA02	NCPDP Provider ID	Situational	Used if supplied, but not required.	AN	7
PHA03	Pharmacy DEA#	Required	Required as the Pharmacy ID.	AN	9
PAT Patier	nt Information				
PAT01	ID Qualifier of Patient Identifier	Situational	Used if supplied but not required. Identifies the jurisdiction of ID used in PAT03	AN	2
PAT02	Patient ID Qualifier	Required	Qualifies ID type used in PAT03. The only allowable values for Kentucky are 06 or 07. • 06 = Driver's License • 07 = Social Security	N	2
PAT03 Patient ID R		Required	ID as specified in PATO2. SSN is required if present. If an adult patient has not been assigned an SSN, driver's license number may be used. If patient does not have SSN or DL, an SSN of all zeros must be used.	AN	20
PAT07	Patient Last Name	Required	Cannot be blank.	AN	50
PAT08	Patient First Name	Required	Cannot be blank.	AN	50
PAT09	Patient Middle Name	Situational	Used if supplied, but not required.	AN	30
PAT10	Prefix	Situational	Used if supplied, but not required.	AN	10
PAT11	Suffix	Situational	Used if supplied, but not required.	AN	10
PAT12	Patient Address 1	Required	Cannot be blank. Note: This should <i>not</i> be a P.O. Box – must be physical address.	AN	35
PAT13	Patient Address 2	Situational	Used if supplied, but not required.	AN	35
PAT14	PAT14 City Required Cannot be blank.		AN	20	
PAT15	State	Required	Cannot be blank. Two character postal code.	AN	10

ASAP 4.2 Element ID	Name	Usage	Specifications	Format	Max Length
PAT16	ZIP Code	Required	Cannot be blank. 5 or 9 digit patient ZIP		9
PAT17	Phone	Situational	Used if supplied, but not required.	AN	10
PAT18	DOB	Required	CCYYMMDD format. Cannot be future and must not be before 1900.	DT	8
PAT19	Gender	Required	 M = Male F = Female U = Unknown 		1
PAT22	Country of Non-U.S. Resident	Situational	Used to identify a patient's country of origin, in case where address is foreign and PAT12-PAT16 are therefore blank.	AN	20
DSP Dispe	nsing Record				
DSP01	Reporting Status	Required	Specifies whether the record is new, revised, or void. 00 = New Record 01 = Revised Record 02 = Void	N	2
DSP02	Prescription Number	Required	RX Number	AN	25
DSP03	Date Written	Required	CCYYMMDD, must be later than Patient DOB (PAT18)	DT	8
DSP04	Refills Authorized	Required	# of refills authorized	N	2
DSP05	Date Filled	Required	CCYYMMDD, must be later than Patient DOB (PAT18)	DT	8
DSP06	Refill Number	Required	0 = first fill 01-99 = refills	N	2
DSP07	Product ID Qualifier	Required	 Use 01 to indicate State required NDC Use 06 to indicate compound that will be identified with CDI fields 	N	2
DSP08	Product ID	Required	NDC with leading zeros and no dashes	AN	15
DSP09	Quantity Dispensed	Required	Metric units dispensed, in metric decimal format.	D	11
DSP10	Days Supply	Required	Estimation	N	3

ASAP 4.2 Element ID	Name	Usage	Specifications	Format	Max Length
DSP16	Classification Code for Payment	Required	Identifies type of payment rendered	N	2
	Туре		■ 01 = Private Pay		
			■ 02 = Medicaid		
			■ 03 = Medicare		
			• 04 = Commercial Insurance		
			■ 05 = Military Installations and VA		
			■ 06 = Workers' Comp		
			■ 07 = Indian Nations		
			■ 99 = Other		
PRE Presc	riber Information				
PRE02	Prescriber DEA Number	Required	Identifying number assigned to the prescriber by the DEA. The prescriber DEA number must begin with the letter A, B, F or M. DEA data waiver numbers starting with the letter X will be rejected. The prescriber's actual DEA number must be reported.	AN	9
CDI Comp	ound Drug Information				
CDI01	Compound Drug Ingredient Sequence Number	Required if Compound	First ingredient must begin with "1" and be incremented by 1 thereafter		2
CDI02	Product ID Qualifier	Required if Compound	Use 01 to indicate State Required NDC	N	2
CDI03	Product ID	Required if Compound	d Product NDC A		15
CDI04	Component Ingredient Quantity	Required if Compound	Metric decimal quantity dispensed	D	11
TP Pharm	acy Trailer				
TP01	Detail Segment Count	Required	Number of detail segments included for the pharmacy (includes PHA and TP)	N	10
TT Transa	ction Trailer				
TT01	Transaction Control Number	Required	Unique transaction number used in TH02	AN	40

ASAP 4.2 Element ID	Name	Usage	Specifications	Format	Max Length
TT02	Segment Count	Required	Total segments in file in including header and trailer	N	10

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4 Upload Reports

After a successful upload, the data file will be parsed by the KASPER system. If it meets success criteria, the data will be loaded into the KASPER system; if not, the data will be rejected and not loaded into the KASPER system.

4.1 Error Thresholds and Tolerances

Submitted data files will be accepted or rejected based on these criteria:

- There are two types of errors:
 - o Minor Incorrect data in non-vital field; record can be loaded
 - Fatal Record cannot be loaded
- An individual record will be rejected if it contains a fatal error.
- As of July 2018, entire files will no longer be rejected for meeting an error threshold. All records will be loaded or rejected on an individual basis.

Important: Data Reporters are **required** to correct fatal errors and resubmit the records within 7 days of the initial record submission.

4.2 Error Correction

When correcting prescription records with errors, here are some guidelines.

- Correcting records with fatal errors should be the highest priority, because those specific records were not loaded into KASPER.
- Records with minor errors are loaded into KASPER, and should be reviewed and corrected as needed.
- When making a correction, it is important to know whether to do so via a record revision, or by voiding the old record and submitting a new one. If one of the following four fields must be changed, then you must void the original and submit a new record:
 - Pharmacy/Dispenser DEA Number
 - o Rx Number
 - Date Filled
 - o NDC Number

Otherwise, you can simply submit a revision of the existing record.

- If you use a vendor pharmacy software system, you probably must do revisions and voids using their software. Contact them if you are unsure of how to do so. If you report your own data to KASPER, you can correct records using the Prescription Data Entry Form detailed in Section 3.2. For error correction, you need to set the Action Type dropdown under Prescription Information to Revise or Void as needed.
- In the event that you find records that require a void or revision whose dates (written
 and/or filled) are older than two years plus the current year, you must <u>contact us</u> to
 temporarily enable an override to allow those records through the record validation
 process.

If you repeatedly receive Edit Code 21 or 21b (NDC Not Found), and you have carefully
verified that the NDC is correct and valid, please contact us to report it, and in most
cases we will be able to get the NDC added to our reference table within a few weeks.

4.3 Upload Notifications

Notification emails are sent to the primary contact's email address, as well as any additional email addresses listed in your account profile, but *not* to the secondary contact's email address.

After KASPER has analyzed and validated the data in your file, a notification email will be sent which provides the following information:

- The total number of records in the data
- The number of fatal and minor errors detected
- Whether or not you are responsible for correcting any issues, and the deadline for doing so

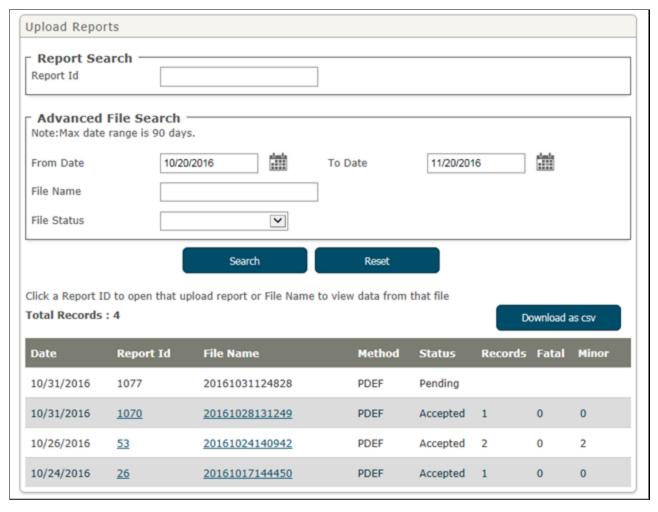
A .csv file containing all details of the upload report will be attached to all emails to allow you to easily review and address the errors. A .csv file can be imported into almost any spreadsheet program. Additionally, the full report can be viewed and downloaded in PDF format from the **Upload Reports** page (see next section).

4.4 Viewing Upload Reports

To view the report in an upload report notification email, click on the link and then sign in to the KASPER Data Reporting site if prompted. Afterwards, the report should open for you to view or save in PDF format.

You can also search for upload reports on the site using the following steps.

- 1. Log in to the KASPER Data Reporting website as directed under Logging In To An Existing Account.
- 2. Select *Upload Reports* from the navigation menu.



- 3. The system will automatically display a table of all of your upload reports from the last 30 days.
 - Click on any **Report ID** link to open that report in PDF format.
 - Click on any **File Name** to open a .csv file containing the data which was parsed from your uploaded file. A .csv file can be opened by any spreadsheet program.
 - If more reports are found than will fit on one page, you will see paging tools at the
 bottom right which allow you to access the full set of reports. You can also click on
 Download As CSV to open a .csv file which contains your search results in a file that
 you can open with any spreadsheet program.
 - To look up a particular report by ID, enter the Report ID in the box at the top and then click **Search**.
 - To search for reports from other time periods, set the **From Date** and **To Date** to the start and end dates of the time period you want, and then click on **Search** to display reports from the given date range.

Note: The maximum date range is 90 days.

• You can also enter a specific filename or select a particular file status from the dropdown menu to further refine your search.

4.4.1 Sample Upload Report



Pharmacy Data Upload Report

Report Id: 6015

File Name: 201606216028A01.dat Uploader: John Smith, M.D. Submission Date: 7/12/2018

Upload Report Data Summary:

1132 records imported on 7/12/2018 13 records rejected - Corrective action required

Total Records: 1145

Records with errors: 57 (5.0%)

Records with FATAL errors, corrective action required: 13 (1.1%)

Records with MINOR errors, corrective action requested: 46 (4.0%)

Duplicate records rejected, no action required: 0

Error Code	Error Description	Incorrect Data	Dispenser DEA	Rx Number	Severity
14z	Void not Found	924137	FF3421283	2605780	Minor
28b	Date Written Irrational	20151119	FF3421283	4613442	Fatal
14z	Void not Found	924423	FF3421283	2605631	Minor
14z	Void not Found	924425	FF3421283	4614392	Minor
21	NDC not found	41167431004	FF3421283	4614468	Minor
54	Customer Zip and State Code conflict	42155	FF3421283	4614040	Minor
54	Customer Zip and State Code conflict	42155	FF3421283	4614039	Minor
14z	Void not Found	924668	FF3421283	2605771	Minor
14z	Void not Found	924671	FF3421283	2605771	Minor
54	Customer Zip and State Code conflict	42144	FF3421283	2605849	Minor

For more details on the error codes and description, refer to the KASPER Controlled Substance Reporting Guide

4.5 Report Edits (Error Codes)

The following error codes are used in upload reports to report errors:

Edit	Message	Severity
01	File Format Error	Fatal

Edit	Message	Severity
02	Dispenser DEA Invalid	Fatal
05	Dispenser ID not found	Fatal
08	Patient ID Invalid	Fatal
09	DOB Invalid	Fatal
09b	DOB Irrational	Fatal
10	Gender Invalid	Minor
14z	Void not found	Minor
15	Date Filled Invalid	Fatal
15b	Date Filled Irrational	Fatal
18	Metric Quantity Invalid	Fatal
18b	Metric Quantity Irrational	Fatal
18c	Metric Quantity Irrational (compound ingredient)	Fatal
19	Days Supply Invalid	Fatal
19b	Days Supply Irrational	Fatal
20	Days Supply Extreme	Minor
21	NDC not found	Minor
21b	NDC not found (compound ingredient)	Minor
22	Product ID Qualifier Invalid	Fatal
25	Prescriber ID not found	Minor
25b	Prescriber ID Invalid	Fatal
28	Date Written Invalid	Fatal
28b	Date Written Irrational	Fatal
29	Number Refills Authorized Invalid	Minor
29b	Refill Number is invalid	Minor
31	Classification Code For Payment Type Invalid	Fatal
50	Customer Last Name Blank	Fatal
51	Customer First Name Blank	Fatal
52	Customer Address Blank	Minor
53	Customer ZIP Code Blank	Fatal
54	Customer ZIP Code and State Conflict	Fatal
56	Customer City Blank	Minor
60	Customer State Code Blank	Fatal
61	Customer State Code Invalid	Minor
200	Prescription Number Blank	Fatal
201	Record Reporting Status Invalid	Fatal
354	Patient ID Qualifier requires value 06 or 07	Fatal
V1	Record Already Exists	Minor

4.5.1 Error Terminology

- In general, the word "Invalid" describes values which are not allowed for a given data field. For example, the field requires a numeric value, but an alphabetic value was provided instead. Generally, most invalid errors are Fatal.
- The word "Irrational" generally indicates that the value provided is out of a defined range. Some of these ranges are defined by the ASAP 4.2 Standard, and others are set by KASPER.

5 KASPER Prescription Upload Support Contacts

5.1 KASPER Prescription Upload Technical Support

Contact the eKASPER Help Desk:

Email address: <u>eKASPERHelp@ky.gov</u>

Phone: 502-564-2703

5.2 KASPER Program Support

Contact the Drug Enforcement and Professional Practices Branch:

Email address: <u>eKASPER.Admin@ky.gov</u>

Phone: 502-564-7985

Address: Drug Enforcement Branch

275 East Main Street, 5E-D

Frankfort, KY 40621

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6 Glossary

ASAP	American Society for Automation in Pharmacy
7.07.1.	
Batch	A group of multiple records sent to KASPER via FTP, secure file upload or
	using the PDEF
DEA Number	The identification number assigned to a prescriber or dispenser by the Drug
	Enforcement Agency
Dispenser	Pharmacy, dispensing pharmacist, or dispensing health care practitioner
	which dispenses controlled substances
eKASPER	The Enhanced Kentucky All Schedule Prescription Electronic Reporting
	program; the name of Kentucky's Prescription Drug monitoring Program
FTP	File Transfer Protocol; commonly-used protocol for exchanging files over any
	network
NDC	National Drug Code; describes specific drugs by drug manufacturer and
	package size
PDMP	Prescription Drug Monitoring Program
PMP	Prescription Monitoring Program
Prescriber	A practitioner who is authorized by state and federal agencies to prescribe
	controlled substances
Prescription Data	Online form for submitting small quantities of data for those without the
Entry Form (PDEF)	means of reporting using data files over SFTP or SSL Upload
SFTP	Secure File Transfer Protocol (also referred to as "SSH File Transfer
	Protocol"); provides file transfer and manipulation functionality over any
	reliable data stream
SSL	Secure Sockets Layer; cryptographic protocol that provides secure
	communications for data transfers
Uploader	Someone who uploads data containing controlled substance dispensing
- p	information, either the dispenser or a third party on behalf of the dispenser
_	The state of the dispersion of the dispersion

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Appendix A. KASPER Statute and Regulation

218A.202 Electronic system for monitoring controlled substances – Required registration and reporting -Penalty for illegal use of system -- Continuing education programs -- Reports of failure to comply with section -Quarterly reviews to identify patterns of improper prescribing or dispensing -- Administrative regulations -ollection and retention of drug conviction data.

- (1) The Cabinet for Health and Family Services shall establish and maintain an electronic system for monitoring Schedules II, III, IV, and V controlled substances. The cabinet may contract for the design, upgrade, or operation of this system if the contract preserves all of the rights, privileges, and protections guaranteed to Kentucky citizens under this chapter and the contract requires that all other aspects of the system be operated in conformity with the requirements of this or any other applicable state or federal law.
- (2) A practitioner or a pharmacist authorized to prescribe or dispense controlled substances to humans shall register with the cabinet to use the system provided for in this section and shall maintain such registration continuously during the practitioner's or pharmacist's term of licensure and shall not have to pay a fee or tax specifically dedicated to the operation of the system.
- (3) Every practitioner or pharmacy which dispenses a controlled substance to a person in Kentucky, or to a person at an address in Kentucky, shall report to the Cabinet for Health and Family Services the data required by this section, which includes the reporting of any Schedule II controlled substance dispensed at a facility licensed by the cabinet and a Schedule II through Schedule V controlled substance regardless of dosage when dispensed by the emergency department of a hospital to an emergency department patient. Reporting shall not be required for:
 (a) A drug administered directly to a patient in a hospital, a resident of a health care facility licensed under KRS Chapter 216B, a resident of a child-caring facility as defined by KRS 199.011, or an individual in a jail, correctional facility, or juvenile detention facility;
- (b) A Schedule III through Schedule V controlled substance dispensed by a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours and is not dispensed by the emergency department of a hospital; or
- (c) A drug administered or dispensed to a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections, where the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health.
- (4) In addition to the data required by subsection (5) of this section, a Kentucky-licensed acute care hospital or critical access hospital shall report to the cabinet all positive toxicology screens that were performed by the hospital's emergency department to evaluate the patient's suspected drug overdose.
- (5) Data for each controlled substance that is reported shall include but not be limited to the following:
- (a) Patient identifier;
- (b) National drug code of the drug dispensed;
- (c) Date of dispensing;
- (d) Quantity dispensed;
- (e) Prescriber; and
- (f) Dispenser.
- (6) The data shall be provided in the electronic format specified by the Cabinet for Health and Family Services unless a waiver has been granted by the cabinet to an individual dispenser. The cabinet shall establish acceptable error tolerance rates for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete or inaccurate data shall be corrected upon notification by the cabinet if the dispenser exceeds these error tolerance rates.
- (7) The Cabinet for Health and Family Services shall only disclose data to persons and entities authorized to receive that data under this section. Disclosure to any other person or entity, including disclosure in the context of a civil action where the disclosure is sought either for the purpose of discovery or for evidence, is prohibited unless specifically authorized by this section. The Cabinet for Health and Family Services shall be authorized to provide data to:

- (a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;
- (b) Employees of the Office of the Inspector General of the Cabinet for Health and Family Services who have successfully completed training for the electronic system and who have been approved to use the system, federal prosecutors, Kentucky Commonwealth's attorneys and assistant Commonwealth's attorneys, county attorneys and assistant county attorneys, a peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer of another state, or a federal agent whose duty is to enforce the laws of this Commonwealth, of another state, or of the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person;
- (c) A state-operated Medicaid program in conformity with subsection (8) of this section;
- (d) A properly convened grand jury pursuant to a subpoena properly issued for the records;
- (e) A practitioner or pharmacist, or employee of the practitioner's or pharmacist's practice acting under the specific direction of the practitioner or pharmacist, who certifies that the requested information is for the purpose of:
- 1. Providing medical or pharmaceutical treatment to a bona fide current or prospective patient;
- 2. Reviewing data on controlled substances that have been reported for the birth mother of an infant who is currently being treated by the practitioner for neonatal abstinence syndrome, or has symptoms that suggest prenatal drug exposure; or
- 3. Reviewing and assessing the individual prescribing or dispensing patterns of the practitioner or pharmacist or to determine the accuracy and completeness of information contained in the monitoring system;
- (f) The chief medical officer of a hospital or long-term-care facility, an employee of the hospital or long-term-care facility as designated by the chief medical officer and who is working under his or her specific direction, or a physician designee if the hospital or facility has no chief medical officer, if the officer, employee, or designee certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current or prospective patient or resident in the hospital or facility;
- (g) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is:
- 1. Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing or dispensing practices;
- 2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring; or
- 3. In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring in that area;
- (h) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Nursing, for any advanced practice registered nurse who is:
- 1. Associated in a partnership or other business entity with a physician who is already under investigation by the Kentucky Board of Medical Licensure for improper prescribing or dispensing practices;
- 2. Associated in a partnership or other business entity with an advanced practice registered nurse who is already under investigation by the Board of Nursing for improper prescribing practices;
- 3. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring; or
- 4. In a designated geographic area for which a report on a physician or another advanced practice registered nurse in that area indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring in that area;
- (i) A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program; or
- (j) A medical examiner engaged in a death investigation pursuant to KRS 72.026.
- (8) The Department for Medicaid Services shall use any data or reports from the system for the purpose of identifying Medicaid providers or recipients whose prescribing, dispensing, or usage of controlled substances may be:
- (a) Appropriately managed by a single outpatient pharmacy or primary care physician; or

- (b) Indicative of improper, inappropriate, or illegal prescribing or dispensing practices by a practitioner or drug seeking by a Medicaid recipient.
- (9) A person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except as provided in this section, in another statute, or by order of a court of competent jurisdiction and only to a person or entity authorized to receive the data or the report under this section, except that:
- (a) A person specified in subsection (7)(b) of this section who is authorized to receive data or a report may share that information with any other persons specified in subsection (7)(b) of this section authorized to receive data or a report if the persons specified in subsection (7)(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each agency engaged in the investigation;
- (b) A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in subsection (7)(a) of this section, or with a law enforcement officer designated in subsection (7)(b) of this section;
- (c) The Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B;
- (d) If a state licensing board as defined in KRS 218A.205 initiates formal disciplinary proceedings against a licensee, and data obtained by the board is relevant to the charges, the board may provide the data to the licensee and his or her counsel, as part of the notice process required by KRS 13B.050, and admit the data as evidence in an administrative hearing conducted pursuant to KRS Chapter 13B, with the board and licensee taking all necessary steps to prevent further disclosure of the data; and
- (e) A practitioner, pharmacist, or employee who obtains data under subsection (7)(e) of this section may share the report with the patient or person authorized to act on the patient's behalf. Any practitioner, pharmacist, or employee who obtains data under subsection (7)(e) of this section may place the report in the patient's medical record, in which case the individual report shall then be deemed a medical record subject to disclosure on the same terms and conditions as an ordinary medical record in lieu of the disclosure restrictions otherwise imposed by this section.
- (10) The Cabinet for Health and Family Services, all peace officers specified in subsection (7)(b) of this section, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.
- (11) The data and any report obtained therefrom shall not be a public record, except that the Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.
- (12) Intentional failure to comply with the reporting requirements of this section shall be a Class B misdemeanor for the first offense and a Class A misdemeanor for each subsequent offense.
- (13) Intentional disclosure of transmitted data to a person not authorized by subsections (7) to (9) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide current or prospective patient or a bona fide specific investigation, shall be a Class B misdemeanor for the first offense and a Class A misdemeanor for each subsequent offense.
- (14) The Cabinet for Health and Family Services may, by promulgating an administrative regulation, limit the length of time that data remain in the electronic system. Any data removed from the system shall be archived and subject to retrieval within a reasonable time after a request from a person authorized to review data under this section.
- (15) (a) The Cabinet for Health and Family Services shall work with each board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances for the development of a continuing education program about the purposes and uses of the electronic system for monitoring established in this section.
- (b) The cabinet shall work with the Kentucky Bar Association for the development of a continuing education program for attorneys about the purposes and uses of the electronic system for monitoring established in this section.

- (c) The cabinet shall work with the Justice and Public Safety Cabinet for the development of a continuing education program for law enforcement officers about the purposes and uses of the electronic system for monitoring established in this section.
- (16) If the cabinet becomes aware of a prescriber's or dispenser's failure to comply with this section, the cabinet shall notify the licensing board or agency responsible for licensing the prescriber or dispenser. The licensing board shall treat the notification as a complaint against the licensee.
- (17) The Cabinet for Health and Family Services, Office of Inspector General, shall conduct quarterly reviews to identify patterns of potential improper, inappropriate, or illegal prescribing or dispensing of a controlled substance. The Office of Inspector General may independently investigate and submit findings and recommendations to the appropriate boards of licensure or other reporting agencies.
- (18) The cabinet shall promulgate administrative regulations to implement the provisions of this section. Included in these administrative regulations shall be:
- (a) An error resolution process allowing a patient to whom a report had been disclosed under subsection (9) of this section to request the correction of inaccurate information contained in the system relating to that patient; and (b) A requirement that data be reported to the system under subsection (3) of this section within one (1) day of dispensing.
- (19) Before July 1, 2018, the Administrative Office of the Courts shall forward data regarding any felony or Class A misdemeanor conviction that involves the trafficking or possession of a controlled substance or other prohibited acts under KRS Chapter 218A for the previous five (5) calendar years to the cabinet for inclusion in the electronic monitoring system established under this section. On or after July 1, 2018 such data shall be forwarded by the Administrative Office of the Courts to the cabinet on a continuing basis. The cabinet shall incorporate the data received into the system so that a query by patient name indicates any prior drug conviction.

Effective: June 29, 2017

History: Amended 2017 Ky. Acts ch. 120, sec. 1, effective June 29, 2017; ch. 138, sec. 1, effective June 29, 2017; and ch. 168, sec. 10, effective June 29, 2017. -- Amended 2013 Ky. Acts ch. 2, sec. 3, effective March 4, 2013. – Amended 2012 (1st Extra. Sess.) Ky. Acts ch. 1, sec. 4, effective July 20, 2012. -- Amended 2010 Ky. Acts ch. 85, sec. 43, effective July 15, 2010. – Amended 2007 Ky. Acts ch. 85, sec. 252, effective June 26, 2007; and ch. 124, sec. 4, effective June 26, 2007. -- Amended 2006 Ky. Acts ch. 5, sec. 5, effective July 12, 2006. -- Amended 2005 Ky. Acts ch. 85, sec. 627, effective June 20, 2005; and ch. 99, sec. 543, effective June 20, 2005. -- Amended 2004 Ky. Acts ch. 68, sec. 1, effective July 13, 2004; and ch. 107, sec. 1, effective July 13, 2004. -- Amended 2002 Ky. Acts ch. 295, sec. 1, effective April 9, 2002. -- Created 1998 Ky. Acts ch. 301, sec. 13, effective July 15, 1998.

Legislative Research Commission Note (6/29/2017). This statute was amended by 2017 Ky. Acts chs. 120, 138, and 168, which do not appear to be in conflict and have been codified together.

Legislative Research Commission Note (7/13/2004). This section was amended by 2004 Ky. Acts chs. 68 and 107. Where these Acts are not in conflict, they have been codified together. Where a conflict exists, Acts ch. 107, which was last enacted by the General Assembly, prevails under KRS 446.250.

902 KAR 55:110. Monitoring system for prescription controlled substances.

RELATES TO: KRS 218A.010(11), 218A.202, 218A.240

STATUTORY AUTHORITY: KRS 194A.050, 218A.202(1), (17), 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.202(1) directs the Cabinet for Health and Family Services to establish and maintain an electronic system for monitoring Schedule II, III, IV, and V controlled substances. KRS 218A.250 requires the cabinet to promulgate administrative regulations pursuant to KRS Chapter 13A for carrying out the provisions of KRS Chapter 218A. This administrative regulation establishes criteria for reporting prescription data, providing reports to authorized persons, and a waiver for a dispenser who does not have an automated recordkeeping system.

Section 1. Definitions. (1) "Branch" means the Drug Enforcement and Professional Practices Branch in the Division of Audits and Investigations, Office of Inspector General, Cabinet for Health and Family Services.

- (2) "Cabinet personnel" means an individual who:
- (a)1. Is directly employed by the Cabinet for Health and Family Services; or
- 2. Is employed by an agent or contractor of the cabinet;
- (b) Has undergone KASPER training; and
- (c) Has been approved to use the KASPER system.
- (3) "Dispenser" is defined by KRS 218A.010(11), and shall:
- (a) Include a dispenser who has a DEA (Drug Enforcement Administration) number or is a pharmacist who owns or is employed by a facility that operates a pharmacy that has a DEA number; and
 - (b) Not include an individual licensed to practice veterinary medicine under KRS Chapter 321.
 - (4) "Health facility" is defined by KRS 216B.015(13).
 - (5) "KASPER" means Kentucky All-Schedule Prescription Electronic Reporting System.
 - (6) "Patient identifier" means a patient's:
 - (a) Full name;
 - (b) Address, including zip code;
 - (c) Date of birth; and
- (d) Social Security number or an alternative identification number established pursuant to Section 5 of this administrative regulation.
 - (7) "Practitioner" is defined by KRS 218A.010(39).
 - (8) "Report" means a compilation of data concerning a patient, dispenser, practitioner, or controlled substance.
 - (9) "Suspected drug overdose" means an acute condition that:
- (a) May include physical illness, coma, mania, or hysteria that is the result of consumption or use of a controlled substance, or another substance with which a controlled substance was combined; and
- (b) Relates to injury, poisoning by, or other adverse effect of any substance corresponding to the following International Classification of Disease (ICD) version 10 (ICD-10) codes, or equivalent codes in the most recent version of the International Statistical Classification of Diseases and Related Health Problems:
 - 1. T40;
 - 2. T42; or
 - 3. T43.

Section 2. Data Reporting. (1) A dispenser or a health facility that has a DEA number shall report all dispensed Schedule II, III, IV, or V controlled substances, except during the circumstances specified in KRS 218A.202(3)(a) through (c).

- (2) A dispenser of a Schedule II, III, IV, or V controlled substance shall transmit or provide the following data to the cabinet or the cabinet's agent:
 - (a) Patient identifier;
 - (b) National drug code of the drug dispensed;
 - (c) Metric quantity of the drug dispensed;
 - (d) Date of dispensing;
 - (e) Estimated days the supply of dispensed medication will last;
 - (f) Drug Enforcement Administration registration number of the prescriber;
 - (g) Prescription number assigned by the dispenser; and

- (h) The Drug Enforcement Administration registration number of the dispenser.
- (3) The data identified in subsection (2) of this section shall be transmitted no later than close of business on the business day immediately following the dispensing unless the cabinet grants an extension as provided in subsection (4) or (5) of this section.
 - (4)(a) An extension may be granted if:
 - 1. The dispenser suffers a mechanical or electronic failure; or
- 2. The dispenser cannot meet the deadline established by subsection (3) of this section because of reasons beyond his or her control.
- (b) A dispenser shall apply to the branch in writing for an extension listed in paragraph (a) of this subsection within twenty-four (24) hours of discovery of the circumstances necessitating the request or on the next date state offices are open for business, following the discovery. An application for an extension shall state the justification for the extension and the period of time for which the extension is necessary.
- (5) An extension shall be granted to a dispenser if the cabinet or its agent is unable to receive electronic reports transmitted by the dispenser.
 - (6) Except as provided in subsection (8) of this section, the data shall be transmitted by:
 - (a) An electronic device compatible with the receiving device of the cabinet or the cabinet's agent;
 - (b) Secure File Transfer Protocol;
 - (c) https protocol; or
 - (d) Secure Virtual Private Network connection.
- (7) The data shall be transmitted in the telecommunications format for controlled substances established by the Implementation Guide, ASAP Standard for Prescription Monitoring Programs, developed by the American Society for Automation in Pharmacy, Version 4.2, or a comparable format approved by the branch.
- (8) A dispenser who does not have an automated recordkeeping system capable of producing an electronic report in the telecommunications format for controlled substances established by the Implementation Guide, ASAP Standard for Prescription Monitoring Programs shall report the data identified in subsection (2) of this section using an Internet accessible web portal designated by the cabinet.
- (9) To meet the reporting requirement of KRS 218A.202(4), a hospital shall report to the cabinet all positive toxicology screens ordered by the hospital's emergency department to evaluate a patient's suspected drug overdose via the Kentucky Health Information Exchange.
- Section 3. Compliance. A dispenser may presume that the patient identification information established in Section 5 of this administrative regulation and provided by the patient or the patient's agent is correct.
- Section 4. Request for Report. (1) A written or electronic request shall be filed with the cabinet prior to the release of a report, except for a subpoena issued by a grand jury or an appropriate court order issued by a court of competent jurisdiction.
 - (2) A request for a KASPER patient report shall be made electronically at www.chfs.ky.gov/KASPER.
- (3) A request for a KASPER provider report made by a peace officer authorized to receive data under KRS 218A.202, or a designated representative of a board responsible for the licensure, regulation, or discipline of prescribing practitioners shall be made by written application on the KASPER Report Request for Law Enforcement and Licensure Boards, Form DCB-20L.
- (4) A medical examiner engaged in a death investigation pursuant to KRS 72.026 may query KASPER for a report on the decedent.
- Section 5. Patient Identification Number. (1) A patient or the person obtaining the controlled substance on behalf of the patient shall disclose to the dispenser the patient's Social Security number for purposes of the dispenser's mandatory reporting to KASPER.
- (2) If a patient is an adult who does not have a Social Security number, the patient's driver's license number shall be disclosed.
- (3) If a patient is an adult who has not been assigned a Social Security number or a driver's license number, the number 000-00-0000 shall be used in the Social Security field.
- (4) If a patient is a child who does not have a Social Security number or a driver's license number, the number "000-00-0000" shall be used in the Social Security field.
 - (5) If a patient is an animal, the number "000-00-0000" shall be used in the Social Security number field.

Section 6. KASPER Data and Trend Reports. Cabinet personnel shall have authorized access to the data obtained from the KASPER system and trend reports in accordance with KRS 218A.240(7)(a).

Section 7. Data Retention. Data shall be maintained in KASPER according to the Office of Inspector General's retention schedule on file with the State Archives and Records Commission.

Section 8. Error Resolution. (1) A patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic to whom a report has been disclosed under KRS 218A.202(9) or this administrative regulation may request that information contained in KASPER be corrected if the patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic believes that any information is inaccurate. The patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic shall:

- (a) Contact the dispenser who reported the information required by Section 2(2) of this administrative regulation; and
 - (b) Request that the dispenser correct the information.
- (2) If, upon receipt of a request from a patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic pursuant to subsection (1) of this section, the dispenser confirms that the information was reported in error, the dispenser shall:
- (a) Transmit corrected information to update the KASPER database within seven (7) calendar days of the request for the correction; and
- (b) Notify the patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic that the corrected information has been transmitted.
- (3) If a dispenser identifies a KASPER system generated error, the dispenser shall notify the branch. Upon verification of the error, the branch shall:
 - (a) Correct the information in the KASPER database; and
- (b) Notify the patient, patient's representative, practitioner, pharmacist, health facility, private practitioner's office or clinic within five (5) working days of the correction.

Section 9. Referrals to Licensing Boards. If the cabinet becomes aware that a prescriber or dispenser has failed to comply with the reporting requirements of KRS 218A.202 and this administrative regulation, the cabinet shall notify the licensing board or agency responsible for licensing the prescriber or dispenser.

Section 10. Disclosure of Data or Report. (1) The cabinet shall only disclose data to the persons and entities authorized to receive that data under KRS 218A.202(7).

- (2) As a condition precedent to the disclosure of data or a report pursuant to KRS 218A.202(7)(f), a hospital or long-term care facility shall maintain, and provide upon request by the cabinet, a copy of the hospital or long-term care facility's policy for the management of KASPER data and reports, which:
- (a) Describes the hospital or long-term care facility's internal procedures for educating the designated employee or employees on the:
 - 1. Proper use of the KASPER system;
 - 2. Prohibition on the improper use or intentional disclosure of KASPER data to unauthorized individuals; and
- 3. Sanctions imposed for the improper use or intentional disclosure of KASPER data to unauthorized individuals, including criminal misdemeanor offenses; and
 - (b) Describes the hospital or long-term care facility's internal procedures for auditing the account, including:
- 1. The manner in which an employee is added to or removed from access to the account if the employee ends employment or is no longer designated to query KASPER; and
- 2. The actions taken if a designated employee with access to the employer's KASPER account intentionally misuses his or her privileges to KASPER data or a report, which shall include a report of the incident to the Office of Inspector General.
- (4)(a) An individual authorized to receive data under KRS 218A.202(7) shall not provide the data to any other entity except as provided in KRS 218A.202(9) and paragraph (b) of this subsection.
- (b) In addition to the purposes authorized under KRS 218A.202(9)(e), and pursuant to KRS 218A.205(2)(a) and (6), a practitioner or pharmacist who obtains KASPER data or a report under KRS 218A.202(7)(e)1. or who in good

faith believes that any person, including a patient, has violated the law in attempting to obtain a prescription for a controlled substance, may report suspected improper or illegal use of a controlled substance to law enforcement or the appropriate licensing board.

(5) A hospital or long-term care facility shall maintain and adhere to the entity's internal policy regarding the management of KASPER data and reports.

Section 11. Incorporation by Reference. (1) The following material is incorporated by reference:

- (a) "Implementation Guide, ASAP Standard for Prescription Monitoring Programs", American Society for Automation in Pharmacy, Version 4.2, September 2011; and
 - (b) "KASPER Report Request for Law Enforcement and Licensure Boards", Form DCB-20L, October 2017.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Drug Enforcement and Professional Practices Branch, Office of the Inspector General, Cabinet for Health and Family Services, 275 E. Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (25 Ky.R. 966; Am. 1367; eff. 12-16-1998; 32 Ky.R. 1927; 33 Ky.R. 120; eff. 7-24-2006; 34 Ky.R. 2609; 35 Ky.R. 283; eff. 9-5-2008; 2615; eff. 7-31-2009; 39 Ky.R. 629; 1218; 1413; 2033; eff. 3-4-2013; 44 Ky.R. 378, 1026, 1346; eff. 1-5-2018.)